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K. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

K024240

510(k) Summary Of Safety and Effectiveness

1.General Information

This Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21 § 807.92

Establishment:

- Address: BD Vacutainer Systems, Preanalytical Solutions
  1 Becton Drive, MC 300
  Franklin Lakes, NJ 07417-1885
- Registration Number: 2243072
- Contact Person: Jing Zhang
  Manager, Regulatory Affairs
  Telephone No.:(201) 847-4717
  Fax No. (201) 847-4858
- Date of Summary: Dec. 20, 2002

Device

- Trade Name: BD Vacutainer™ PLUS Plastic Urine C&S Preservative Tubes and Kits
- Classification Name: Aerobic Transport System (Microbiological specimen collection and transport device)
- Classification: Class I
- Performance Standards: None Established under 514 of the Food, Drug and Cosmetic Act

2. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

- Device Description:

The BD Vacutainer™ PLUS Plastic Urine C&S Preservative Tube is a sterile, plastic, evacuated urine collection and transport tube for culture and sensitivity testing of bacteria. The benefits of a plastic tube decrease the occurrence of accidental breakage increases the safety of laboratory personnel and reduces the necessity of repeat specimens.

- Intended Use/Indications for Use:

The BD Vacutainer™ PLUS Plastic Urine C&S Preservative Tubes and kits are intended for the collection and transport of urine samples for culture and sensitivity testing of bacteria.

The BD Vacutainer™ PLUS Plastic Urine C&S Preservative Tube is filled with lyophilized urine maintenance formula and evacuated to draw approximately 4 – 10 mL (depending on the tube size) of urine. The lyophilized urine maintenance formula can maintain the bacterial population in the urine specimen for a period of 48 hours at room temperature levels comparable to those urine specimens without additive, held under refrigeration for the same period of time.

- Synopsis of Test Methods and Results

Extensive functional and clinical evaluations were performed to determine the safety and efficacy of the BD Vacutainer™ PLUS Plastic Urine C&S Preservative Tubes and kits. They were compared to the currently marketed BD Vacutainer™ Brand non-additive tube and Glass Urine C&S Preservative Tubes and kits. The results of the tests demonstrated that the BD Vacutainer™ PLUS Plastic Urine C&S Preservative Tubes provide functionally and clinically equivalent results when compared to the BD Vacutainer™ Brand non-additive tubes and Glass Urine C&S Preservative Tubes.

- Substantial Equivalence

Based on comparison of the device features, materials, and intended use, the BD Vacutainer™ PLUS Plastic Urine C&S Preservative Tubes can be shown to be substantially equivalent to the commercially available predicate device identified below:

Manufacturer	Predicate Device	K-Number	Clearance Date
BD Vacutainer Systems, Preanalytical Solutions	BD Vacutainer™ Brand Glass Urine C&S Preservative Tubes and Kits	K790336	4/4/79

Jing Zhang
Manager, Regulatory Affairs

12/20/02
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 6 2003

Mr. Jing Zhang
Manager, Regulatory Affairs
Becton, Dickson and company
BD Vacutainer Systems, Preanalytical Solutions
1 Becton Drive
Franklin Lakes, NJ 07417

Re: k024240
Trade/Device Name: BD Vacutainer ™ PLUS Plastic Urine C&S Tubes and Kits
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport Culture Medium
Regulatory Class: Class I
Product Code: JSM
Dated: December 20, 2002
Received: December 23, 2002

Dear Mr. Zhang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

C. INDICATIONS FOR USE

510(k) Number (if known): K024240

Device Name: BD Vacutainer™ PLUS Plastic Urine C&S Tubes and Kits

Indications for Use:

The BD Vacutainer™ PLUS Plastic Urine C&S Preservative Tubes and Kits are intended for the collection and transport of urine samples for culture and sensitivity testing of bacteria.

The BD Vacutainer™ PLUS Plastic Urine C&S Preservative Tube is filled with lyophilized urine maintenance formula and evacuated to draw approximately 4 - 10 mL (depending on the tube size) of urine. The lyophilized urine maintenance formula can maintain the bacterial population in the urine specimen for a period of 48 hours at room temperature levels comparable to those urine specimens without additive, held under refrigeration for the same period of time.

(Please do not write below this line-continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-the-Counter Use_____
(Per 21 CFR § 801.109) (Optional format 1-2-96)

Freddie Tu Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K024246